

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN N-
NITROSODIMETHYLAMINE (NDMA)
CONTAMINATION PRODUCTS LIABILITY
LITIGATION

Civil No. 19-2875 (RBK/JS)

ORDER¹

The Court having held a discovery conference with the parties on November 20, 2019 to address the "macro" discovery issues listed in the Court's October 22, 2019 Order [Doc. No. 280]; and the matters in dispute only addressing discovery issues addressed to the API and Finished Dose Manufacturing Defendants (hereinafter collectively referred to as "defendants"); and this Order intending to incorporate the Court's rulings reflected in its Oral Opinion issued after the completion of oral argument; and for all the reasons stated by the Court on the record,

IT IS HEREBY ORDERED this 25th day of November, 2019, that by December 4, 2019, plaintiffs and defendants shall serve simultaneous letter briefs on the issue of whether the Court should strike defendants' redactions on the FDA documents produced to plaintiffs. Plaintiffs shall promptly identify for defendants

¹ This corrected Order replaces the Order originally put on the docket on November 25, 2019.

twenty (20) representative redacted documents for the Court to review in camera. Defendants shall serve with their letter briefs for the Court's in camera review redacted and unredacted copies of the documents plaintiffs designate as well as twenty (20) representative documents defendants designate; and it is further

ORDERED by December 31, 2019, defendants shall produce and/or make available for plaintiffs' inspection all documents produced and/or made available to the FDA for its inspection during the FDA's inspections of defendants' API and finished dose manufacturing facilities (hereinafter collectively referred to as "facilities"), or produced or made available for inspection by the FDA concerning the Valsartan recall; and it is further

ORDERED plaintiffs shall promptly advise the Court when Aurobindo and Hetero are served pursuant to the Hague Convention; and it is further,

ORDERED the general January, 2020, in-person conferences are rescheduled to January 28, 2020, at 10:00 a.m. and 2:00 p.m.; and it is further

ORDERED the Court incorporates by reference all rulings set forth in its November 20, 2019 Oral Opinion that are set forth in the transcript of proceedings; and it is further

ORDERED as follows:

1. Plaintiffs' request to strike defendants' objections to plaintiffs' written discovery is DENIED.

2. As to defendants, the facilities at issue for discovery purposes are the facilities that manufactured Valsartan API and Valsartan sold in the United States, not just the facilities that sold recalled Valsartan.
3. By December 2, 2019, defendants shall identify the complete names and addresses of each of their facilities that are subject to discovery, and the inclusive dates Valsartan API and Valsartan were made.
4. Plaintiffs' request for discovery regarding other products using the same manufacturing processes, solvents, and testing as those for Valsartan API is DENIED. However, defendants shall produce all documents reflecting the presence of any nitrosamine in any sartan product. This includes not only Valsartan but also Losartan, Irbesartan, Olmesartan and Candesartan.
5. Plaintiffs' requests for copies of defendants' litigation hold letters or emails is DENIED. However, by December 31, 2019, defendants shall identify all recipients of the hold letters and emails, the sender, and when the letters or emails were sent. Further, plaintiffs may address ESI preservation issues with defendants' deponents.
6. Plaintiffs' request for foreign regulatory documents is GRANTED in part and DENIED in part. Plaintiffs' request for all foreign regulatory documents sent or received regarding Valsartan and the Valsartan recall is DENIED. However, for each relevant facility the defendants shall produce by December 31, 2019, all regulatory inspection reports, warning letters akin to what the FDA sends, 483-like documents, the responses to these documents, root cause analyses regarding the Valsartan contamination, and documents regarding potential or actual nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.
7. Plaintiffs' request for foreign sales, marketing materials and agreements is DENIED. However, to the extent defendants are in possession, custody, or control of documents from any source regarding unknown and unidentified testing peaks or general toxic impurities in Valsartan API or Valsartan, the documents shall be produced.

8. The parties shall meet and confer prior to the December 11, 2019 conference concerning all disputes regarding the testing documents to be produced. Plaintiffs are entitled to discovery regarding any test that could identify the presence of nitrosamine contamination. Also, testing and results regarding other carcinogens, general toxic impurities, or residual solvents in the Valsartan API and Valsartan is relevant. In advance of the December 11, 2019 conference, defendants shall identify the types and purposes of the tests done on Valsartan API and Valsartan.
9. Defendants shall produce all documents, communications and studies, etc. regarding the health effects of exposure to Valsartan or Valsartan API contaminated with nitrosamines. Plaintiffs' request for health effect discovery regarding non-contaminated Valsartan is DENIED.
10. The relevant time period for general custodial discovery as to defendants is as follows:

ZHP - 1/1/10 to present
Mylan - 1/1/11 to present
Teva - 1/1/12 to present
Torrent - 1/1/13 to present
Aurolife/Aurobindo - 1/1/12 to present

This designation is without prejudice to plaintiffs' right to request older specific documents or categories of documents, upon a showing of good cause.

11. In connection with defendants' document production, defendants shall produce a translated version of documents that have already been translated in the normal course of defendants' business.

s/ Joel Schneider
JOEL SCHNEIDER
United States Magistrate Judge